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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/717,243

11/18/2003

Marc D. Better

11022US16

8820

7590

03/30/2006

Janet M. McNicholas, Ph.D.
McAndrews, Held & Malloy, Ltd.
500 W. Madison Street, 34th Floor
Chicago, IL 60661

EXAMINER

HUYNH, PHUONG N

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/717,243	Applicant(s) BETTER ET AL.	
	Examiner Phuong Huynh	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/6/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-13 are pending.
2. The following new grounds of rejections are necessitated by the amendment filed 12/6/05.
3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of the (1) binding specificity of any antibody, any antibody such as any single chain antibody or any region of any antibody comprising an antigen-binding portion in the claimed fusion protein, and (2) any “region” of any antibody “comprising” any antigen-binding portion such as Fab fragment, Fd fragment, F(ab')sub2, any Fab' fragment, and (3) any “kappa fragment” in the claimed fusion protein.

The specification discloses only a fusion protein comprising gelonin comprising the amino acid sequence of SEQ ID NO: 2 or SEQ ID NO: 101 fused to an antibody or antigen binding portion thereof that binds specifically to human CD5. The said antibody is denoted as he3. The said fusion protein wherein the antigen binding portion thereof *is* a Fab fragment, F(ab')sub2, Fd fragment, or a single chain antibody.

With the exception of the specific antibody or the binding fragment thereof fused to the gelonin comprising the amino acid sequence of SEQ ID NO: 2 or 101 mentioned above, there is insufficient written description about the binding specificity of any and all antibody or any region of any antibody comprising an antigen binding portion in the claimed fusion protein. Further, there is insufficient written description about the structure associated with function of any and all “region” of an antibody comprising any antigen-binding portion without the amino acid sequence. The term “comprising” is open-ended. It expands the binding region of the antibody to include

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additional amino acids at either or both ends. There is inadequate written description about the amino acid to be added.

Likewise, there is inadequate written description about the structure associated with function of "kappa fragment" without the amino acid sequence. Since the binding specificity of the antibody and the structure of the region of an antibody in the claimed fusion protein are not adequately described, it follows that any fusion protein further comprising a peptide segment of a shiga-like toxin as in SEQ IDN O: 56 between said gelonin and antibody or said region is not adequately described. It also follows that any fusion protein further comprising a peptide segment of a rabbit muscle adldoase as in SEQ IDN O: 57 or SEQ ID NO: 59 between said gelonin and said antibody or said region is not adequately described.

The specification discloses only one antibody that binds specifically to human CD5 fused to a gelonin comprising the amino acid sequence of SE QID NO: 2 or 101, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species of antibody, region of all antibody, and kappa fragment to describe the genus for the claimed fusion protein. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co. 43 USPQ2d 1398; University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (CA FC2004).*

Applicant is directed to the Final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The "antibody or region of an antibody comprising an antigen-binding portion" in the claimed fusion protein as set forth in claims 1 and 4-9 is ambiguous and indefinite because the binding specificity of said antibody or region of said antibody is not recited in the claimed. Further, it is not clear which "region" of an antigen binding portion in claims 1 and 3-9 is part of

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the claimed fusion protein. One of ordinary skilled in the art cannot appraise the metes and bound of the claimed invention.

7. No claim is allowed.
8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.
10. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phuong N. Huynh, Ph.D.

Application/Control Number: 10/717,243

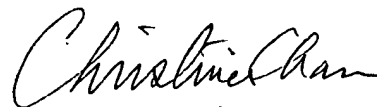
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Patent Examiner

Technology Center 1600

March 17, 2006

A handwritten signature in black ink, appearing to read "Christina Chan". The signature is fluid and cursive, with the first name "Christina" being more prominent than the last name "Chan".

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600